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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/938,641 08/27/2001 211226US0X Achim Marx 2808 10/06/2003 EXAMINER 22850 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. KERR, KATHLEEN M 1940 DUKE STREET ALEXANDRIA, VA 22314 ART UNIT PAPER NUMBER 1652

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)		
		09/938,641	MARX ET AL.		
	Office Action Summary	Examiner	Art Unit	_	
•	Kathleen M Kerr	1652			
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with	the correspondence address	_	
THE - Extending after - If the - If NO - Failure - Any	ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. e period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply within the statutory minimum of thirty (3 rill apply and will expire SIX (6) MONTHS cause the application to become ABAN	be timely filed O) days will be considered timely. From the mailing date of this communication.		
	Responsive to accommissation (a) filed as 00 (
1)	Responsive to communication(s) filed on <u>09 J</u>	· ··			
2a) □	,	s action is non-final.			
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims					
•	Claim(s) <u>1-38</u> is/are pending in the application				
	4a) Of the above claim(s) 7-9,23-25 and 30-38 is/are withdrawn from consideration.				
5)					
	☐ Claim(s) <u>1-6,10-22 and 26-29</u> is/are rejected.				
	Claim(s) are subject to restriction and/or	election requirement			
	on Papers	election requirement.			
9)🛛	The specification is objected to by the Examiner				
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
	Applicant may not request that any objection to the				
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.					
If approved, corrected drawings are required in reply to this Office action.					
12)☐ The oath or declaration is objected to by the Examiner.					
Pri rity u	nder 35 U.S.C. §§ 119 and 120				
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a)⊠ All b)□ Some * c)□ None of:					
	1. Certified copies of the priority documents have been received.				
	2. Certified copies of the priority documents have been received in Application No				
	3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).				
	ee the attached detailed Office action for a list of				
	14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).				
a) 15)∐ A	☐ The translation of the foreign language provices the comment of the comment	visional application has been c priority under 35 U.S.C. §§	received. 120 and/or 121.		
Attachment	• •				
2) 🔲 Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> .	5) Notice of Infor	mary (PTO-413) Paper No(s) mal Patent Application (PTO-152) intinuation Sheet .		

Continuation of Attachment(s) 6). Other: Taxonomy Browser and alignments.

DETAILED ACTION

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Application Status

1. In response to the previous Office action, a written restriction requirement (Paper No. 5, mailed on June 10, 2003), Applicants filed an election received on June 9, 2003 (Paper No. 7). Claims 1-38 are pending in the instant Office action.

Election

2. Applicant's election with traverse of Group I, Claims 1-6, 10-22, and 26-29 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the Office has not demonstrated adequate reasons of patentably distinctness among the groups. Particularly, Applicants argue that Group II is, in fact, related to Groups I and III-IV, contrary to the Office's assertion, because they are both claims in the same general field, i.e., biotechnology. This is not found persuasive because while Group II and Groups I and III-IV are in the field of biotechnology, the structures and functions of the products claimed are wholly distinct as previously noted. Group II is drawn to a generic *E. coli-C. glutamicum* shuttle vector without any relation to the DNA of OxyR disclosed in the application other than how the vector can be used to transform the *C. glutamicum* gene into *E. coli*.

Applicants argue that Groups I-V can be reasonably searched in the same technical field.

This is not found persuasive because the text search, sequence searches, and class/subclass searches are not co-extensive for the names Groups.

Applicants argue that the product and process of use relationship between Group I and Groups III-IV is "merely stated as an unsupported conclusion". This is not the case because the

Examiner previously cited an alternate use for the product as required by M.P.E.P. § 806.05(h). This alternate use is materially different having distinct method steps from methods of screening polynucleotides and methods of making amino acids, as clearly evidenced by the distinct class/subclass classifications cited. Applicants argue this same point for Groups I and V; however, this is not a valid argument because Groups I and V are distinct products, unrelated to methods, except by way of further showing distinctness. The real distinction comes from their different structures and functions as previously noted.

Applicants argue that the Office called Groups I and IV unrelated; this is not the case; Groups II and IV were considered unrelated for the reasons maintained above for the distinctness of Group II from Groups I and III-IV.

Applicants argue that Groups III and IV are described as unrelated; this is not the case.

These Groups were noted as related by virtue of the DNA used in the methods. These methods were also noted as being distinct based on the distinct method steps and products. Groups III and IV were noted as being related to Group V because the DNA that encodes the proteins of Group V is used in the methods of Groups III-IV. However, the polypeptides were noted as being neither made nor used in the method Groups.

Applicants finally argue that no search burden exists because Groups I-IV are all classified in class 435. Applicants failed to note that different subclasses are noted for each of these Groups. A search of more than one subclass is considered burdensome since the searches are not co-extensive. Moreover, as previously noted, different sequence searches and text-based literature searches are required for each of the noted Groups I-V. For all these reasons, the claims cannot be examined together without an undue burden on the Office.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-38 are pending in the instant application. Claims 7-9, 23-25, and 30-38 are withdrawn from consideration as non-elected inventions. Claims 1-6, 10-22, and 26-29 will be examined herein.

Priority

3. The instant application is granted the benefit of U.S. Provisional Application 60/279,415 filed on March 29, 2001 in the declaration; however, without a certified translation of this document, filed in German, this earlier effective filing date cannot be granted for subject matter of the pending claims since support in the priority document cannot be ascertained.

The instant application is also granted the benefit of foreign applications 10042052.4 and 10110053.1 filed in Germany on August 26, 2000 and March 2, 2001. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119(a)-(d), which papers have been placed of record in the file. Said papers are in German. While this foreign priority is granted, the claims cannot be granted either of these filing dates without a certified translation of the priority document(s) since support in the priority document cannot be ascertained.

Thus, the earliest effective filing date of the claims examined herein is August 27, 2001.

Information Disclosure Statement

The information disclosure statement filed on February 2, 2002 (Paper No. 4) has been 4. reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy. Corrections made by the Examiner will appear in the citations on the front of any patent granted from the instant application.

The information disclosure statement filed on July 9, 2003 (Paper No. 6) has been reviewed, and its references (related cases) have been considered. No PTO-1449 was filed. Application/Control Number: 09/938,641 Page 5

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Objections to the Specification

5. In the specification, the Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion of the source species, *Corynebacterium glutamicum*, for completeness.

6. The specification is objected to for lacking updated U.S. patent application citations. On page 12, lines 5 and 13, applications are cited that are now U.S. patents 6,569,650 and 6,586,214, respectively. Correction is required.

Objections to the Claims

- 7. Claims 2 and 18 are objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. SEQ ID NO:2 is disclosed in the instant specification as having OxyR transcriptional regulator activity; thus, this feature is inherent in the polynucleotide of Claims 1 and 11 and cannot further limit the subject matter of the claim.
- 8. Claims 5, 6, 21, 22, and 27-28 are objected to for using an improper genus/species name. In Claims 5, 21, 27, and 28, "Coryneform" in italics indicates a genus name; however, this is a vernacular name for the genus ---Corynebacterium---. In Claims 6 and 22, "Coryneform glutamicum" should be ---Corynebacterium glutamicum---. Correction is required.

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9. Claim 12 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 11 is drawn to SEQ ID NO:1, which is described as a DNA sequence – DNA being a double stranded molecule. Thus, a "complimentary" polynucleotide in no way further limits the DNA. For proper further limiting parameters, the claim must be drawn to a polynucleotide that is the full complement of the coding strand of SEO ID NO:1.

10. Claims 13-17 are objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Each of Claims 13-15 broadens the subject matter of Claim 11 by allowing alterations within SEQ ID NO:1 (within a certain % identity). Claim 16 broadens Claim 11 by requiring only a short oligomer of SEQ ID NO:1 and not the full-length sequence. Claim 17 broadens Claim 11 by claiming any polynucleotide that hybridizes to SEQ ID NO:1. Each of the claims can be rewritten as independent claims for correct claim structure; the instant claims will be examined as if they are independent claims related to SEQ ID NO:1.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 2 and 18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. The term "OxyR transcriptional regulator activity" is unclear. What does an OxyR protein do? How is this function tested? What, if any, structural features help define the function? Clarification is required.

- 12. Claims 6 and 22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Markush group is unclear because it contains overlapping members. The species "Brevibacterium lactofermentum" and "Brevibacterium divaricatum" are synonyms for --- Corynebacterium glutamicum--- (see attachment of Taxonomy Browser), already in the Markush group. Thus, the nature of these two species is unclear. All other species are clearly found in the art by means of the Taxonomy Browser and/or the ATCC collection. Correction is required.
- 13. Claim 17 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "washing", which relates conditions, is confusing in view of the specification and the art. These very low stringency conditions are typically used in a hybridization step (allowing everything to stick) followed by a more stringent washing step that removes "false-positives". Moreover, on page 9, these conditions are noted as hybridization conditions, not wash conditions. Clarification is required.
- 14. Claim 27 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. The phrase "enhanced expression of the oxyR gene" (emphasis added) is unclear. The article "the" indicates a single gene, but multiple options for the oxyR gene are implied by the further limiting claim 28. Also, must the oxyR gene that is enhanced be the endogenous Corynebacterium oxyR gene of the cell claimed (if the cell is C. glutamicum, must enhancement be of a C. glutamicum oxyR gene or can an oxyR gene from C. melassecola be added to meet the limitations of the claim)? Only one example of an oxyR gene is described in the instant specification – that of C. glutamicum (SEQ ID NO:1 encoding SEQ ID NO:2). Particularly in view of the dependent Claim 28, the metes and bounds of the scope of the oxyR gene are unclear. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 13-17 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 13-17 are drawn to polynucleotides having at least 70% identity with or having a consecutive fragment of SEQ ID NO:1; no function of the claimed polynucleotide is a limitation in the instant claims.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a

precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification describes polynucleotides encoding OxyR transcriptional regulator polypeptides. Applicants have fully described the genus relating to said SEQ ID NOs with both sequence identity limitations and functional limitations (i.e., having OxyR transcriptional regulator function), albeit unclear functional limitations as noted above. However, the genus of the instant claims also contains polynucleotides within the sequence identity or fragment limitations, but having different function. Applicants have not fully described a genus that has sequence identity or fragment limitations in the absence of functional limitations.

16. Claim 27 is rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 27 is drawn to bacterium

with enhanced expression of a gene that is claimed solely by function (name) and without any structural limitations.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification describes a C. glutamicum host cell with enhanced expression of the C. glutamicum oxyR gene by virtue of transformation of the gene on a plasmid into the host cell. In the claim, the gene is only described according to the functional characteristics of the enzymes they encode; no structural relationship is described or used in the claims. Thus, one of skill in the art would be unable to predict the structure of other members of this genus by virtue of the instant disclosure. Therefore, claims drawn to bacteria containing the genus of said genes are also not adequately described.

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17. Claims 13-17 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for polynucleotides that encode SEQ ID NO:2, does not reasonably provide enablement for polynucleotides structurally related to SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. To use such polynucleotides would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

The instant specification describes a polynucleotide (SEQ ID NO:1) that encodes SEQ ID NO:2, an OxyR transcriptional regulator. The scope of the instant claims includes structurally related polynucleotides that are not necessarily functionally related. The specification has not enabled the use of structurally related polynucleotides, wherein the encoded polypeptides have a different function. No guidance or working examples are described for how to use structurally, but not functionally, related polynucleotides. The specification focuses on overexpressing the OxyR protein for the production of lysine in *C. glutamicum*; this use is not viable with a polynucleotide encoding a polypeptide not having OxyR protein function. The nature of the invention is such the function of the encoded polypeptide is crucial to its use. Thus, in the absence of such a limitation, the instant claims are not enabled to the full extent of their scope.

18. Claims 27-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for coryneform host cells that overexpress the *C. glutamicum oxyR* gene, does not reasonably provide enablement for coryneform host cells with enhanced expression of said gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. To make such host cells would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized above.

In the specification on page 6, "enhancement" is described as increasing the activity of the encoded protein by, for example, (1) increasing the copy number of the gene expressed in the cell, (2) putting the gene under the control of a stronger promoter, and (3) expressing a gene encoding a protein with higher activity. While the specification is enabled for overexpression

(items 1 and 2, as understood in the art), the specification is not enabled for expressing a higher activity protein. None is disclosed in the specification or the art. The specification provides no guidance or working examples for the identification of such a protein. The ability to produce a gene encoding such a protein is wholly unpredictable. Thus, the instant claims are not enabled to the full extent of their scope.

19. Claim 29 is rejected under 35 U.S.C. § 112, first paragraph, enabling deposit, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. To use the instant product, one of skill in the art is required to have DSM 13457 which is disclosed as C. glutamicum DSM5715 containing pT-oxyRexp. Thus, the plasmid or the description and availability of all its components for its construction must be publicly available. While the instant specification contains limited deposit information on page 6, the requirements to enable such a deposit have not been fully met by the instant application. To enable the instant claims by enabling the deposit of DSM 13457, the following items are required: (1) the accession number assigned by the depository, (2) the date of deposit, (3) a brief description of the deposit, (4) the name and full address of the depository (37 C.F.R. § 1.801 - 1.809) (those which are in bold have not been fulfilled by the instant specification), and (5) the record must also contain a statement certifying that all restrictions on accessibility to said deposit be irrevocably removed by Applicant upon the granting of the patent (see M.P.E.P. § 2404.01); this statement may be certified by Applicants or Applicants' representative.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 20. Claims 1-6, 10-22, and 26-28 are rejected under 35 U.S.C. § 102(a) as being anticipated by Nakagawa *et al.* (EP 1108790-see IDS). The instant claims are drawn to a polynucleotide that is SEQ ID NO:1, vectors and *C. glutamicum* host cells thereof as well as methods of using SEQ ID NO:1 to produce the encoded protein.

Nakagawa *et al.* teach SEQ ID NO:7065 that is identical to SEQ ID NO:1 from 228687-230361 base pairs (see attached alignment). Nakagawa *et al.* also teach vectors, specific host cells, and methods of making the encoded protein (see pages 4 and 8).

21. Claim 16 is rejected under 35 U.S.C. § 102(b) as being anticipated by GenBank Accession Number AE001274 (*Leishmania* major chromosome 1, complete sequence, May 19, 1998). The instant claims are drawn to a polynucleotide comprising a fragment of SEQ ID NO:1 that is at least 15 consecutive nucleotides.

GenBank Accession Number AE001274 teaches a DNA sequence that contains 23 consecutive nucleotides of SEQ ID NO:1, from 926-948 (see attached alignment).

22. Claim 17 is rejected under 35 U.S.C. § 102(b) as being anticipated by either GenBank Accession Number AF186371 or U18263 (see IDS). The instant claims are drawn to a

polynucleotide that hybridizes to SEQ ID NO:1 under very low stringency conditions as defined in the claim.

GenBank Accession Number AF186371 teaches an S. *coelicolor oxyR* gene that has 54% similarity to SEQ ID NO:1 (see attached alignment). Based on this similarity and the overall affinity DNA has for other DNA under the low stringency conditions provided in Claim 17, the DNA taught by GenBank Accession Number AF186371 meets the limitations of Claim 17.

GenBank Accession Number U18263 teaches an *M. avium oxyR* gene that has 55% similarity to SEQ ID NO:1 (see attached alignment). Based on this similarity and the overall affinity DNA has for other DNA under the low stringency conditions provided in Claim 17, the DNA taught by GenBank Accession Number U18263 meets the limitations of Claim 17.

Conclusion

23. Claims 1-6, 10-22 and 26-29 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK

Kathfolor 9/30/07